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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,699

04/21/2004

Karen M. Cheves

1001.1705101

5388

28075 7590 02/05/2010
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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

02/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/828,699	Applicant(s) CHEVES ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed 10/22/2009.
2. Claim 15 was amended.
3. Thus, claim 15 is pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al (2004/0243156).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

5. Wu et al discloses a cutting balloon catheter (Fig 2), comprising: an elongate catheter shaft 12; a balloon (114) coupled to the shaft, the balloon having a first inflated

configuration and a second non-inflated configuration (Fig 2-4), wherein the balloon has a plurality of substantially smooth wings formed therein when in the second configuration (Fig 2-4; [0030]; and response to arguments below); a metallic cutting blade (16) for severing or breaking up a lesion affixed to the balloon (Fig 2-4; Summary), the cutting blade including means for cutting having two intersecting planes which form a cutting edge, including means for gripping thereon and having a longitudinal axis (16; Fig 2-4), and having a cross-sectional shape that is substantially triangular in a plane traverse to the longitudinal axis (16; Fig 2-4); wherein the means for cutting and means for gripping are defined by a series of undulations (16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42) on the cutting blade; and wherein the undulations curve from side-to-side relative to the longitudinal axis (16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42).

6. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Shaw et al (7279002). Shaw et al discloses a cutting balloon catheter (Summary; Fig 12), comprising: an elongate catheter shaft (Fig 12); a balloon (152) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration (Fig 25; col 7-8), wherein the balloon has a plurality of substantially smooth wings formed therein when in the second configuration (Fig 25); a metallic cutting blade (104; Fig 3) for severing or breaking up a lesion affixed to the balloon (col 3, lns 57-col 4; wherein the Examiner notes that the "affixed to the balloon" means that the metallic cutting blade

is attached physically to the balloon in some manner -- the cutting blade 104 on stent 100 is attached to the balloon during use), the cutting blade including means for cutting having two intersecting planes which form a cutting edge, including means for gripping thereon and having a longitudinal axis (104; Fig 3, 5), and having a cross-sectional shape that is substantially triangular in a plane traverse to the longitudinal axis (104; Fig 3, 5); wherein the means for cutting and means for gripping are defined by a series of undulations (104; Fig 3) on the cutting blade; and wherein the undulations curve from side-to-side relative to the longitudinal axis (104; Fig 3).

Response to Arguments

Applicant's arguments with respect to claim 15 have been considered but are not persuasive.

7. The Applicant argues that:

- i. Wu does not teach substantially smooth walls.
- ii. Shaw does not teach a metallic cutting blade affixed to the balloon.

8. In response to (i), the Examiner notes that Wu discloses:

[0030] Wings 42 may also include one or more undulations or an undulating surface as indicated in FIG. 2 by reference number 44. In general, undulations 44 may resemble waves or peaks and valleys formed in wings 42. In some embodiments, the "peaks" of undulations 44 line up along the longitudinal axis of balloon 14. However, this need not be the case. Additionally, the number, arrangements, and position of undulations 44 may vary in different example embodiments as well as among the different wings 42 of a particular embodiment. For example, some example wings 42 may include relatively few undulations 44 while other example wings 42 may include several. Moreover, some wing

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42 embodiments may include undulations 44 that have opposing "peaks" similar to what is shown in FIG. 3, while other wings 42 may include nesting or aligned peaks or any other suitable configuration. (emphasis added)

9. Thus, while undulations are contemplated, they are not necessarily included on the wings 42, leaving the resulting wings substantially smooth.

10. Alternatively, "substantially smooth" is a relative term that would appear to still be met by the undulations (44) as shown in Fig 3. All undulations 44 shown in Fig 3 appear rounded, lacking sharp points or angles, and thus substantially smooth. The rejection is maintained.

11. In response to (ii), the Examiner notes that Merriam Webster's Dictionary defines affixed as "to be attached physically" and "to attach in any way." There is no claim requirement that the cutting blade be affixed to the balloon throughout the entire use of the device. The cutting blade (104) on the stent 100 of Shaw is mounted on the balloon and thus is attached physically to the balloon which is within the scope of "affixed" to the balloon. As, Shaw meets every claim limitation, the rejection is maintained.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767